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NOV 14

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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,808,665

NOTICE OF FINAL DETERMINATION OF INELIGIBILITY

A determination has been made that U.S. Patent No. 5,808,665, which claims the medical device da VINCI™ System, is ineligible for patent term extension under 35 U.S.C. § 156.

The application for patent term extension is dismissed.

A single request for reconsideration of this final determination as to eligibility of the patent for extension may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR 1.136(a) are applicable to this time period.

An application for patent term extension was filed on Monday, September 11, 2000, based upon the regulatory review of the product da VINCI™ System, which was approved on July 11, 2000. Sixty days after the approval date of the product was Saturday, September 9, 2000. 35 U.S.C. 156(d)(1) requires an application for patent term extension to be filed within sixty days of product approval. 35 U.S.C. 21(b) states that:

> When the day, or the last day, for taking any action or paying any fee in the United States Patent and Trademark Office falls on Saturday, Sunday, or a federal holiday within the District of Columbia, the action may be taken, or the fee paid, on the next succeeding secular or business day.

Monday, September 11, 2000 was the next succeeding business day following the last day (September 9, 2000), accordingly, the application for patent term extension was timely filed.

35 U.S.C. § 156(a) also provides (in part) that:

> The term of a patent which claims a product...shall be extended in accordance with this section ...if--
> ...(4) the product has been subject to a regulatory review period before its commercial marketing

35 U.S.C. § 156(g) defines the term regulatory review period, as it applies to medical devices

> For purposes of this section, the term "regulatory review period" has the following meanings:
>
> ...(3)(A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.
> (B) The regulatory review period for a medical device is the sum of--
> (i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and
> (ii) the period beginning on the date an application was initially submitted with respect to

the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

The medical device da VINCI™ system underwent regulatory review under Section 510(k) of the Federal Food, Drug and Cosmetic Act (FFDCA). For regulatory review of a medical device claimed by a patent to give rise to eligibility for patent term extension, the regulatory review must have been under Section 515 of the FFDCA. See 35 U.S.C. § 156(g)(3)(A). Since the regulatory review of VINCI™ system was under Section 510(k), not Section 515, the patent is not eligible for patent term extension. See Manual of Patent Examining Procedure, Section 2751, page 2700-14, Eighth edition (August 2001), citing In re Nitinol Medical Technologies Inc., 17 USPQ2d 1492, 1492-1493 (Comm'r Pat. & Tm. 1990). See also Baxter Diagnostics v. AVL Scientific Corp., 798 F. Supp. 612, 619-620; 25 USPQ2d 1428, 1434 (1992)(Congress intended only Class III medical devices to be eligible for patent term extension).

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 872-9411
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159. E-mail inquiries should be directed to Karin.Tyson@uspto.gov.

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
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RE: da VINCI System
FDA Docket No.: 01E-0096

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Date:	Client & Matter Number :	No. Pages (including this one):
December 19, 2001	**017516-007400US**	**3**
To: **Karin Tyson** Office of Patent legal Administration/ Office of the Deputy Asistant Commissioner for Patent Policy and Projects	At Fax Number: **1.703.872.9411**	Confirmation Phone Number: **1.703.308.6202**

From : Nena Bains **(5240)**

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